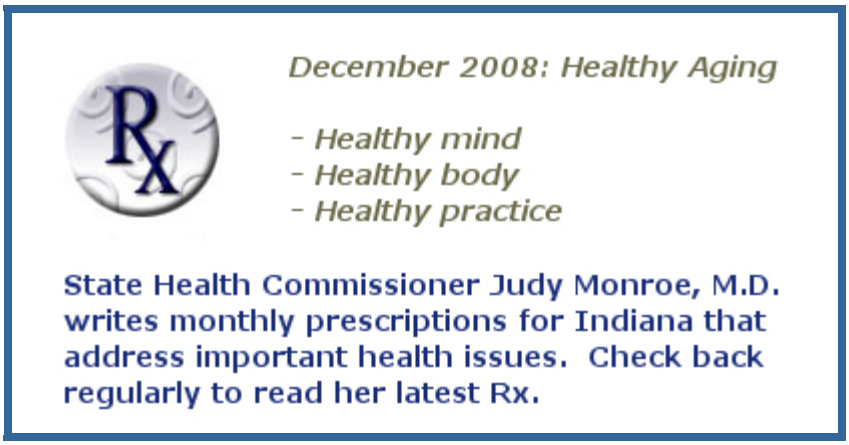
Long Term Care NEWSLETTER

Indiana State Department of Health

ISDH Long Term Care Newsletter Issue # 08-33
December 15, 2008

In Today's Issue:
- Residential Care Rules
- Recall Alerts
- CMS Flu Reference



Residential Care Health Facility Rules

The Indiana State Department of Health (ISDH) Division of Long Term Care is in the process of developing a report card for the state licensed free-standing Residential Care Health Facilities. To prepare for this endeavor, the residential care rules have been formatted to resemble the F-tag system used for surveys of federally certified facilities.

Beginning December 15, 2008, any state rule violations cited on a survey report of a Residential Care Health Facility will be identified with an "R" and a number that corresponds to the specific state residential rule. Attached are the R-tag designations with the correlating residential care rule. Surveyors have piloted this new system for approximately three months. All residential care facility surveys beginning on or after December 15, 2008, will be using the R-tags for the survey report.

Please note that the state residential health facility rules have not changed. The rules have just been formatted with an identifying R-tag has been assigned to each rule.

If you have any questions, please contact Sue Hornstein at 317-233-7289

Recall Alert: Potassium Chloride

From information provided by the U.S. Food and Drug Administration (FDA), the recalled product was distributed nationwide. Hospitals, medical centers, and long term care facilities may carry this product. Detailed distribution information is not available at this time.

Dec. 8, 2008 -- Hospira, Inc., a global specialty pharmaceutical and medication delivery company, is following up on a nationwide voluntary recall issued Sept. 18 of one lot (lot number 65-620-FW, expiration date May 1, 2010, NDC 0409-7902-09) of 20 mEq Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP in 1000 mL flexible plastic containers because a small number of

the containers may be incorrectly labeled with a bar code for 5% Dextrose Injection, USP (NDC 0409-7922-09). The incorrect bar code could lead to a medication error resulting in the wrong drug being delivered to a patient if a bar code system is used to confirm the medication. Potential adverse events related to an error of this type include electrolyte imbalance, cardiac dysfunction, gastrointestinal disturbances, paresthesia and mental confusion.

The product contains 20 mEq Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride. The product name and National Drug Code (NDC) number printed on the container are correct. The affected lot was shipped to U.S. customers between July 2008 and September 2008. No other lots are affected by this recall.

Hospira has not received any reports of adverse health events in connection with the recalled lot. Hospira has identified the root cause of the error and taken action to prevent its recurrence.

The Weblink for this recall is: http://www.fda.gov/medwatch/safety/2008/safety08.htm#20meqPotChlor.

Recall Alert: AMO Fill Size Syringes

This product is intended for intraocular use as a surgical aid in ophthalmic surgical procedures. This product was manufactured from September 1, 2008 through September 30, 2008 and distributed from September 1, 2008 through October 29, 2008.

December 11, 2008 - Advanced Medical Optics (AMO), Inc. and FDA notified healthcare professionals of a recall of Healon D Ophthalmic Viscosurgical Device, Lot Number UD30654, 30 mg/mL fill size syringes. Some of the tested OVD syringes had endotoxin levels above the required limit. These higher levels may cause intraocular inflammation and/or Toxic Anterior Segment Syndrome in patients following surgery. Healthcare professionals should stop using and remove from their inventory all units of the affected lot and contact AMO at 1-877-266-4543.

The Weblink for this recall is: http://www.fda.gov/medwatch/safety/2008/safety08.htm#Healon

Recall Alert: Oversized Tablets

ETHEX Corporation Initiated Nationwide Voluntary Recalls of Specific Lots of Five Generic Products Due to the Potential for Oversized Tablets

Propafenone HCl Tablets - 150 mg, 225 mg, and 300 mg
Isosorbide Mononitrate Extended Release Tablets – 30 mg and 60 mg
Morphine Sulfate Extended Release Tablets - 15 mg
Morphine Sulfate Immediate Release Tablets - 15 mg and 30 mg
Dextroamphetamine Sulfate Tablets - 10 mg

November 7, 2008 – ETHEX Corporation announced today that it has voluntarily recalled to the consumer level specific lots of five generic /non-branded products that it markets. These lots have been recalled as a precaution, due to the possibility that they may contain oversized tablets. Oversized tablets may contain more than the intended levels of the active drug ingredient, which could result in patients receiving as much as about twice the expected dosage of these drugs.

Overdoses of Propafenone HCl, Isosorbide Mononitrate, Morphine sulfate and Dextroamphetamine Sulfate can have serious or life-threatening consequences. In the case of Propafenone HCl, these consequences can include arrhythmias (irregular heartbeat) and low blood pressure. In the case of Isosorbide Mononitrate, these consequences can include fainting and low blood pressure. In the case of Morphine Sulfate, these consequences can include respiratory depression (difficulty or lack of breathing)

and low blood pressure. In the case of Dextroamphetamine Sulfate, these consequences can include rapid heart rate and high blood pressure.

The lots involved in the recall were all shipped prior to May 22, 2008 and are listed on the Weblink at http://www.fda.gov/oc/po/firmrecalls/ethex11_08.html.

A CMS Quick Reference Information Resource for Flu Season

Flu Season Is Here! Medicare provides coverage of the flu vaccine without any out-of-pocket costs to Medicare patients. No deductible or copayment/coinsurance applies. For quick information to assist with filing claims for the influenza vaccine and it's administration, the Centers for Medicare & Medicaid Services (CMS) has prepared ***The Quick Reference Information: Medicare Part B Immunization Billing*** **Chart (Feb. 2008) -** This two-sided laminated reference chart gives Medicare fee-for-service physicians, providers, suppliers, and other health care professionals a quick reference to coding and billing information. To view, download, and print the quick reference chart, go to *http://www.cms.hhs.gov/MLNProducts/downloads/qr_immun_bill.pdf* on the CMS website. To order a copy, free of charge, go to the MLN Products Ordering web page at *http://cms.meridianksi.com/kc/pfs/pfs_lnkfrm_fl.asp?lgnfrm=reqprod&function=pfs* .

Get Your Flu Shot – Not the Flu.

Vist www.inshape.in.gov to find out how you can Move More, Eat Better, and Stop Smoking.

That is all for this week.

Terry Whitson
Assistant Commissioner
Indiana State Department of Health